IN THE CIRCUIT COURT OF THE 11TH
JUDICIAL CIRCUIT, IN AND FOR
MIAMI-DADE COUNTY, FLORIDA
CASE NO.: 2021-021945 CA 01

ALEXANDER OMAR VALDES
AS PERSONAL REPRESENTATIVE
FOR THE ESTATE OF TERESA VALDES,

Plaintiff,

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.;
BOEHRINGER INGELHEIM CORPORATION;
BOEHRINGER INGELHEIM USA CORPORATION;
PFIZER INC.;
SANOFI-AVENTIS U.S. LLC;
SANOFI US SERVICES INC.;
GLAXOSMITHKLINE LLC;
GLAXOSMITHKLINE HOLDINGS (AMERICAS) INC.;
and
PUBLIX SUPER MARKETS, INC.

Defendants.
_____/

FOURTH AMENDED COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL[1]

Plaintiff Alexander Omar Valdes, as Personal Representative of the Estate of Teresa Valdes, Decedent, by and through undersigned counsel, hereby sues the following Defendants: Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Corporation; Boehringer Ingelheim USA Corporation; Pfizer Inc.; Sanofi-Aventis U.S. LLC; Sanofi US Services Inc.; GlaxoSmithKline LLC; GlaxoSmithKline Holdings (Americas) Inc.; and Publix Super Markets, Inc. Plaintiff alleges:

[1] This Fourth Amended Complaint is filed pursuant to the Court's Order dated June 13, 2023. The only substantive changes were to modify Counts I and II (Failure to Warn) and remove Count VIII (Civil Conspiracy), pursuant to the Order. Other editorial changes were made to correct erroneous count and paragraph numbering.

JURISDICTION AND VENUE

1. This is an action for damages in excess of $30,000.00, exclusive of interest, costs, and attorneys' fees.

2. Decedent, Teresa Valdes, was at all times mentioned herein a resident of Miami-Dade County, Florida.

3. This action is brought, in part, pursuant to the provisions of the Florida Wrongful Death Act § 768.16, et seq., Florida Statutes, for the wrongful death of Decedent, Teresa Valdes.

4. Decedent Teresa Valdes (hereinafter "Decedent" or "Ms. Valdes") died on July 27, 2022, from colorectal cancer, which was first diagnosed in August 2018.

5. Plaintiff Alexander Omar Valdes (hereinafter "Plaintiff" or "Mr. Valdes"), son of Decedent, was appointed the Personal Representative of Ms. Valdes' estate on September 21, 2022. See *In RE: Valdes, Teresa Vera*, 2022-004658-CP-02, Sec. PMH05, Cir. Ct. of the 11th Jud. Cir, Miami-Dade Cty, FL. The Order Appointing Mr. Valdez as Personal Representative of Ms. Valdes' estate and the corresponding Letters of Administration are attached hereto as Exhibit A. As the Personal Representative of Decedent's estate, Mr. Valdes hereby stands in as Decedent's representative in this suit. Fla. Stat § 733.608.

6. As a direct and proximate result of Decedent's injury and wrongful death, the Estate and Plaintiff have suffered damages as follows:

a. Alexander Omar Valdes has suffered mental pain and injury over the death of his mother, and he will continue to suffer mental pain and anguish over the injury and death of his mother as long as he lives;

b. The Estate of Decedent has suffered medical and funeral expenses resulting from the injury and wrongful death of Decedent;

c. The Estate of Decedent has suffered loss of support and services from Decedent, Teresa Valdes; and,

d. Decedent's Estate has suffered a loss of net accumulations.

7. At all relevant times and as further alleged in detail, Defendants Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Corporation; Boehringer Ingelheim USA Corporation; Pfizer Inc.; Sanofi-Aventis U.S. LLC; Sanofi US Services Inc.; GlaxoSmithKline LLC; and GlaxoSmithKline Holdings (Americas) Inc. (hereinafter collectively referred to as the "Manufacturer Defendants") conducted business within the State of Florida and specifically, Miami-Dade County Florida. Each of the Manufacturer Defendants derived substantial revenue from manufacturing, marketing, handling, distributing, storing, and selling ranitidine-containing products, specifically over-the-counter brand-name Zantac (hereafter referred to as "OTC Zantac"), within the State of Florida and specifically, Miami-Dade County, Florida.

8. At all relevant times and as further alleged in detail, Defendant Publix Super Markets, Inc. conducted business within the State of Florida and specifically, Miami-Dade County Florida. Publix Super Markets, Inc. derived substantial revenue from marketing, handling, distributing, storing, and selling ranitidine-containing products, specifically OTC Zantac, within the State of Florida and specifically, Miami-Dade County, Florida.

THE DECEDENT'S CLAIM

9. During the 1990s through 2018, Decedent Teresa Valdes purchased and ingested OTC Zantac which was manufactured by each of the Manufacturer Defendants to treat her symptoms of heartburn, acid indigestion, and other gastrointestinal conditions.

10. During the 1990s through 2018, Decedent purchased the OTC Zantac she ingested from Publix Super Markets, Inc.

11. The OTC Zantac that Decedent purchased and ingested contained dangerous levels of the chemical ranitidine and N-Nitrosodimethylamine ("NDMA") and after ingestion some of

the ranitidine created more NDMA in Decedent's body. The OTC Zantac that Decedent purchased and ingested caused Decedent to develop colorectal cancer.

12. Decedent purchased OTC Zantac at Publix Super Markets, Inc. in such quantities and with such frequency that the amount of OTC Zantac that Decedent purchased at Publix was a substantial contributing cause of Decedent's colorectal cancer and the injuries alleged herein.

13. Decedent purchased and ingested OTC Zantac that was manufactured by the Manufacturer Defendants in such quantities and with such frequency that the amount of OTC Zantac that she purchased and ingested that was manufactured by each of the individual Manufacturer Defendants was, from each individual manufacturer, a substantial contributing cause of Decedent's colorectal cancer and the injuries alleged herein.

14. The OTC Zantac that Decedent purchased and ingested that was manufactured by the Manufacturer Defendants and sold to Decedent by Publix Super Markets, Inc. was a direct and legal proximate cause of Decedent's colorectal cancer and the injuries and death alleged herein.

THE MANUFACTURER DEFENDANTS

Boehringer Ingelheim

15. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a citizen of Delaware and Connecticut.

16. Defendant Boehringer Ingelheim Corporation is a Nevada corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim Corporation is a citizen of Nevada and Connecticut.

17. Defendant Boehringer Ingelheim USA Corporation is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgebury, Connecticut 06877.

Boehringer Ingelheim USA Corporation is a citizen of Delaware and Connecticut.

18. Defendants Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Corporation; and Boehringer Ingelheim USA Corporation shall collectively be referred to as "Boehringer Ingelheim".

Pfizer

19. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is a citizen of Delaware and New York.

Sanofi

20. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC's sole member is Sanofi U.S. Services Inc., a Delaware corporation with its principal place of business in New Jersey. Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey.

21. Defendant Sanofi US Services Inc. is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services Inc. is a citizen of Delaware and New Jersey.

22. Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. shall collectively be referred to as "Sanofi."

GlaxoSmithKline

23. Defendant GlaxoSmithKline LLC is a Delaware limited liability company with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania, 19112. GlaxoSmithKline LLC's sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware

corporation with its principal place of business in that state. GlaxoSmithKline LLC is a citizen of Delaware.

24. Defendant GlaxoSmithKline Holdings (Americas) Inc. is a Delaware corporation with its principal place of business located at 1105 N. Market Street, Suite 622, Wilmington, Delaware 19801. Defendant GlaxoSmithKline Holdings (Americas) Inc. is a citizen of Delaware.

25. GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc. are subsidiaries of GlaxoSmithKline plc. Collectively, these entities shall be referred to as "GlaxoSmithKline".

PUBLIX SUPER MARKETS, INC.

26. Defendant Publix Supermarkets, Inc. ("Publix") is a Florida corporation with its principal place of business located at 3300 Publix Corporate Parkway, Lakeland, Florida 33811. Publix is a citizen of Florida.

THE DEFECTIVE ZANTAC PRODUCT

27. At all relevant times during which Decedent purchased and ingested OTC Zantac from the 1990s to 2018, the OTC Zantac that Decedent purchased and ingested was manufactured and/or distributed and/or sold by one or more of the Manufacturer Defendants.

28. Each of the Manufacturer Defendants owed a duty to Decedent and the public in general to assure that OTC Zantac remained safe and free from any defects and/or unreasonable risks of danger to the consumers such as Decedent who would purchase and ingest OTC Zantac. Each of the Manufacturer Defendants breached their duties to Decedent and the public in general.

29. At all times relevant hereto each of the Defendants knew or should have known—as further explained in detail—that OTC Zantac contained the active ingredient ranitidine. A derivative compound of ranitidine is N-Nitrosodimethylamine ("NDMA"), a well-known and

dangerous carcinogen. As further explained herein, certain amounts of NDMA are inherent in the manufacture of OTC Zantac, and then, once ranitidine is ingested, additional NDMA is created in greater amounts and in greater dangerous quantities in the stomach and intestines and in other parts of the human body. Hence, OTC Zantac itself is a cancer-causing substance when used as intended by consumers such as Decedent.

30. At all relevant times hereto, the cancer-causing properties of OTC Zantac were known to the Manufacturer Defendants and Publix.

31. At all relevant times hereto, the cancer-causing properties of OTC Zantac were unknown by ordinary consumers such as Decedent and were far beyond the reasonable expectations of the ordinary consumer such as Decedent. OTC Zantac was at all relevant times hereto a defective product.

FACTUAL ALLEGATIONS

I. AN OVERVIEW OF THE SCIENCE OF THE CARCINOGEN, NDMA

32. Until its recent recall (2019) by the United States Food and Drug Administration (FDA), Zantac was a popular antacid drug consumed by millions of people every day. Recent scientific studies, however, confirm what the Manufacturer Defendants and Publix knew or should have known decades earlier: ingesting ranitidine and therefore OTC Zantac exposes the consumer of OTC Zantac to staggering amounts of NDMA.

33. NDMA is a potent human carcinogen. It was first discovered in the early 1900s as a by-product of manufacturing rocket fuel. Today, its only use is to induce tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no medicinal purpose whatsoever.

34. NDMA is not akin to other compounds that have a salutary effect at low levels and

a negative effect with greater exposure. There is no recommended daily dose of NDMA. The ideal level of exposure is zero. Nonetheless, the FDA previously set an allowable daily limit of NDMA of 96 nanograms (ng) to minimize the risks posed by this dangerous molecule. Yet a single tablet of ranitidine or Zantac can contain quantities of NDMA that are hundreds of times higher than the allowable limit.

35. Those recent revelations by the scientific community have caused widespread recalls brand-name Zantac and generic ranitidine both domestically and internationally. In fact, after numerous voluntary recalls, on April 1, 2020, the FDA ordered the immediate withdrawal of all ranitidine-containing products sold in the United States, citing unacceptable and unpreventable levels of NDMA accumulation.

36. The high levels of NDMA observed in OTC Zantac and ranitidine-containing products are a function of the drug's unstable nature. Ranitidine-containing products generate NDMA as the ranitidine molecule (1) breaks down in the human digestive system; (2) interacts with various enzymes in the human body; (3) reacts over time under normal storage conditions and which increases significantly when exposed to heat; and/or (4) during the manufacturing process. In aggregate, OTC Zantac and ranitidine-containing products were akin to billions of "Trojan Horses" that smuggled dangerously high levels of NDMA into the bodies of millions of consumers.

II. THE DISCOVERY OF RANITIDINE AND RANITIDINE'S DERIVATIVE CARCINOGEN, NDMA

37. Brand-name Zantac was originally created by one of GlaxoSmithKline's predecessor corporations named Allen & Hanburys, Ltd. In 1976, scientist John Bradshaw, on behalf of GlaxoSmithKline's predecessor Allen & Hanburys, Ltd., synthesized and discovered ranitidine.

38. Allen & Hanburys, Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule. In 1983, the FDA granted approval of New Drug Application ("NDA") 18-703 under section 505(b) of the Food Drug and Cosmetic Act ("FDCA") to GlaxoSmithKline to sell ranitidine under the brand name "Zantac."

39. According to the Environmental Protection Agency ("EPA"), "NDMA is a semi volatile organic chemical that forms in both industrial and natural processes." It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far." NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

40. Both the EPA and the International Agency for Research on Cancer ("IARC") classify NDMA as a probable human carcinogen.

41. The IARC classification is based upon data that demonstrates NDMA "is carcinogenic in all animal species tested: mice, rats, Syrian gold, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, various fish, newts and frog. It induces benign and malignant tumors following its administration by various routes, including ingestion and inhalation, in various organs in various species." Further, in 1978, IARC stated that NDMA "should be regarded for practical purposes as if it were carcinogenic to humans."

42. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.

43. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen. This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring in several sites, including but not limited to the liver, respiratory tract, kidney, and blood vessels.

44. The FDA considers NDMA a chemical that "could cause cancer" in humans.

45. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."

46. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

47. The no-observed-adverse-effect level ("NOAEL") is the level of exposure at which there is no biologically significant increase in the frequency or severity of any adverse effects of the chemical. Due to NDMA's ability to affect DNA at a microscopic level, there is no NOAEL for NDMA. This means that any amount of NDMA exposure increases risk.

48. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 ng is considered unacceptable.

49. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, cancers were observed in the liver, pancreas, and stomach. In comparable guinea-pig studies, cancers were observed in the liver and lung. In comparable rabbit studies, cancers were observed in the liver

and lung.

50. In other long-term animal studies in mice and rats utilizing different routes of exposures— inhalation, subcutaneous injection, and intraperitoneal (abdomen injection)—cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

51. NDMA is a very small molecule, which allows it to freely pass through all areas of the body, including the blood-brain and placental barrier. This is particularly concerning as ranitidine has been marketed for pregnant women and young children for years.

52. In addition, NDMA breaks down into various derivative molecules that, themselves, are associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestine (including colon). Further studies have shown that there is a significant positive association with the intake of NDMA and the subsequent occurrence of colorectal cancer and that NDMA causes and can induce colorectal cancer in humans.

53. Research shows that lower levels of NDMA, e.g., 40 ng, are fully metabolized in the liver, but high doses enter the body's general circulation.

54. Exposure to high levels of NDMA has been linked to liver damage in humans.

55. Numerous in vitro studies confirm that NDMA is a mutagen—causing mutations in human and animal cells.

56. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and frogs.

57. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."

58. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."

59. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. And, while these studies consistently show increased risks of various cancers, the exposure levels considered in these studies are a very small fraction of the exposures noted in a single ranitidine tablet or pill.

III. A HISTORY OF CORPORATE ACQUISITIONS, AGREEMENTS, AND THE MARKETING OF ZANTAC

60. In 1983, once the FDA granted approval to GlaxoSmithKline to sell ranitidine under the brand name Zantac, pursuant to NDA 18-703, it quickly became GlaxoSmithKline's most successful product. Indeed, ranitidine became the first prescription drug in history to reach $1 Billion in sales.

61. To get to that goal, GlaxoSmithKline entered into a joint promotion agreement with Hoffmann-LaRoche, Inc., which increased Zantac's U.S. sales force from 400 people to approximately 1,200. More salespersons drove more sales and more profits for GlaxoSmithKline.

62. In 1993, GlaxoSmithKline entered into a joint venture with Pfizer-predecessor company Warner-Lambert Co. to develop an OTC version of Zantac. In 1995, the FDA granted 505(b) approval to Zantac 75 mg tablets through NDA 20-520, which was issued to GlaxoSmithKline's predecessor, Glaxo Wellcome, Inc.

63. All OTC Zantac formulations were submitted and approved as new NDAs under § 505(b) of the FDCA:

a. NDA 20-520 was approved by the FDA on December 19, 1995, and was issued to Glaxo Wellcome, Inc.;

b. NDA 20-745 was approved by the FDA on February 26, 1998, and was issued to Glaxo Wellcome, Inc.; and

c. NDA 21-698 was approved by the FDA on September 31, 2004, and was issued to Pfizer.

64. Subsequent formulations and variations of OTC Zantac were approved by the FDA as supplemental submissions under the heading of the above-listed NDAs.

65. In 1998, GlaxoSmithKline and Warner-Lambert Co. ended their joint venture. As part of the separation, Warner-Lambert Co. retained control over the OTC NDAs for Zantac and the Zantac trademark in the United States and Canada but was required to obtain approval from GlaxoSmithKline prior to making any product or trademark improvements or changes. GlaxoSmithKline retained rights to sell OTC Zantac outside of the United States and Canada, and it retained control over the Zantac trademark internationally.

66. GlaxoSmithKline's retention of the right to require GlaxoSmithKline's approval for any product improvements or changes came with an inherent duty on the part of GlaxoSmithKline to assure that OTC Zantac remained safe and free from any defects and/or unreasonable risks of danger to the consumers who would ingest OTC Zantac.

67. In June 2000, Pfizer acquired Warner-Lambert Co. and, thereafter, Pfizer controlled the OTC Zantac NDAs until December 2006.

68. In October 2000, GlaxoSmithKline sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GlaxoSmithKline divested all domestic OTC Zantac assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GlaxoSmithKline retained the right to

the exclusive use of the Zantac name for any prescription ranitidine-containing product in the United States.

69. Throughout the time that Pfizer controlled the NDAs for OTC Zantac, GlaxoSmithKline continued to manufacture the product.

70. In 2006, pursuant to a Stock and Asset Purchase Agreement, Pfizer sold and divested its entire consumer health division (including employees and documents) to Johnson & Johnson ("J&J"). Because of antitrust issues, however, OTC Zantac was transferred to Boehringer Ingelheim.

71. Pfizer, through a divestiture agreement, transferred all assets pertaining to its OTC Zantac line of products, including the rights to sell and market all formulations of OTC Zantac in the United States and Canada, as well as all intellectual property, R&D, and customer and supply contracts to Boehringer Ingelheim. As part of that deal, Boehringer Ingelheim obtained control and responsibility over all of the OTC Zantac NDAs.

72. GlaxoSmithKline continued marketing prescription Zantac in the United States until 2017, and it still holds the NDAs for several prescription formulations of Zantac. GlaxoSmithKline continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac.

73. Boehringer Ingelheim owned and controlled the NDAs for OTC Zantac between December 2006 and January 2017, and Boehringer Ingelheim manufactured, marketed, and distributed the drug in the United States during that period.

74. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to an asset swap agreement. As part of that deal, Sanofi obtained control and responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs.

As part of this agreement, Boehringer Ingelheim and Sanofi entered into a manufacturing agreement wherein Boehringer continued to manufacture OTC Zantac for Sanofi. Sanofi has controlled the OTC Zantac NDAs and marketed, sold, and distributed Zantac in the United States from January 2017 until 2019 when it issued a recall and ceased marketing, selling, and distributing OTC Zantac.

75. Sanofi voluntarily recalled all brand-name OTC Zantac on October 18, 2019.

IV. ALL OF THE MANUFACTURER DEFENDANTS KNEW (OR SHOULD HAVE KNOWN) THAT RANITIDINE WOULD CAUSE THE FORMATION OF NDMA

76. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, The Lancet. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects." Dr. de Flora hypothesized that these mutagenic effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to … suggest [] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals."

77. GlaxoSmithKline knew of Dr. de Flora's publication because, two weeks later, GlaxoSmithKline responded in The Lancet, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (i.e., NDMA) were not likely to be experienced by people in the real world.

78. GlaxoSmithKline's response reflects its approach to the scientific evidence on the dangers of Zantac as "adopting the most combative, scorched-earth positions in defense of its brands." The company has no compunctions against distorting objective science to maintain its

lucrative monopoly franchises, and its egregious conduct surrounding Zantac is not some isolated incident.

79. As early as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA from Zantac when properly tested. This was known or should have been known by the Defendants or any other manufacturer or distributor of ranitidine-containing products as the information was available in medical literature. Such literature should have been accessed by all companies in the chain of distribution of ranitidine, even if it would have been difficult to locate for a regular consumer.

80. In 1981, GlaxoSmithKline, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography. Many metabolites were listed, though there is no indication that the study looked for NDMA.

81. Indeed, in that same year, Dr. de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body. GlaxoSmithKline was aware of this study because GlaxoSmithKline specifically responded to the note and attempted to discredit it. Defendants knew or should have known about this scientific exchange as it was published in a popular scientific journal. Defendants were obligated to investigate this issue properly. None did.

82. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GlaxoSmithKline published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds. That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was rigged. It used an analytical system called a “nitrogen oxide assay” for the determination of N-

nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Not only is that approach not accurate, but GlaxoSmithKline also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was known or should have been known to all Defendants in light of its scientific publication in 1987. All Defendants either knew or should have known about the inadequacy of that study, and all Defendants should have investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products. None did.

V. GLAXOSMITHKLINE DEBATES THE SCIENCE AND OBSTRUCTS FULL, COMPLETE, AND TRUTHFUL CONSUMER EXPECTATIONS ABOUT THE SAFETY OF RANITIDINE A/K/A ZANTAC

83. In its original pre-approval submission to the FDA, GlaxoSmithKline explained that the level of nitrite present in Zantac would be unrealistic and, thus, these results had no "practical clinical significance." Specifically, GlaxoSmithKline stated:

> Although N-nistroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as un unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

84. Around this same time—***before Zantac was approved by the FDA***—GlaxoSmithKline conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach. Remarkably, in the study that was presented to the FDA, GlaxoSmithKline admitted that ranitidine use caused the proliferation

of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GlaxoSmithKline acknowledged this could increase the risk of developing NDMA and, in turn, cancer, but it then dismissed this risk because individuals were allegedly only expected to use ranitidine-containing products for a short-term period. In particular, GlaxoSmithKline stated:

> The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

85. GlaxoSmithKline knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form NDMA and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach.

86. In response to Dr. de Flora's findings, in 1982, GlaxoSmithKline conducted a clinical study specifically investigating gastric contents in human patients. The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GlaxoSmithKline indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. That study, however, was also rigged. GlaxoSmithKline did not use gold-standard mass spectrometry to test for NDMA; it instead used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GlaxoSmithKline refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." In other words, GlaxoSmithKline intentionally rigged the study to exclude the very samples most likely to contain a dangerous carcinogen.

87. In 1983, the same year GlaxoSmithKline obtained approval for Zantac from the FDA, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA). The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells."

88. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings. Dr. de Flora and his colleagues concluded that the results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine." Again, the authors noted that "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." This admonition carries weight considering GlaxoSmithKline's studies indicate that long- term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

89. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed. These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-treatment plants that supply many U.S. cities with water.

90. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 ng of NDMA per day. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng

of NDMA per day. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer in individuals who were exposed to 0.179 ng of NDMA per day.

91. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "N-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.

92. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, pharynx, prostate, and brain cancer.

93. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow-up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.

94. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.

95. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant (i.e. not malignant) cancers, (2) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer. Thus, in addition to NDMA being a direct cause

of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

96. NDMA is also known to be genotoxic, which means it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both in vivo and in vitro. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."

VI. NDMA BECOMES WIDELY KNOWN AS A PROVEN CAUSE OF CANCER AND ZANTAC IS REMOVED FROM THE MARKET

97. In 2016, researchers at Stanford University conducted an experiment on healthy volunteers. The researchers measured the NDMA in urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. On average, the level of NDMA increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. This study directly demonstrates that unsafe levels of NDMA are formed in the human body as a result of ranitidine ingestion. The scientists further explained that previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. As such, the observed 47,000 ng likely only captured 1/100 of the actual NDMA levels in the human body.

98. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and Valisure RX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all ranitidine-containing products due to exceedingly high levels of NDMA found in ranitidine tablets. FDA and European regulators started reviewing the safety of ranitidine with specific focus on the presence

of NDMA. This set off a cascade of recalls by the Defendants and other sellers of ranitidine products.

99. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement warning that some ranitidine medicines may contain NDMA.

100. Beginning in September 2019, various generic manufacturers of ranitidine-containing products began recalling their generic forms of their Zantac equivalent. Some retailers also stopped selling Zantac and other ranitidine-containing products.

101. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using a liquid chromatography with high resolution mass spectrometer ("LC-HRMS") testing protocol, which "does not use elevated temperature."

102. On October 8, 2019, Manufacturer Defendant GlaxoSmithKline voluntarily recalled all ranitidine-containing products internationally. As part of the recall, GlaxoSmithKline publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that "GlaxoSmithKline is continuing with investigations into the potential source of the NDMA."

103. In October 2019, additional generic manufacturers of ranitidine-containing products continued to announce recalls of their Zantac equivalents.

104. On November 1, 2019, the FDA announced the results of recent testing, finding "unacceptable levels" of NDMA in ranitidine-containing products, and requested that drug makers begin to voluntarily recall their ranitidine-containing products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.

105. On December 4, 2019, the FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, e.g., processed meats and preservatives like sodium nitrite. This advice mirrored an admonition

issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites in vitro to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. de Flora published in October 1981 in The Lancet was to "avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals or by giving inhibitors of nitrosation such as ascorbic acid."

106. Between November 1, 2019 and February 27, 2020, more generic manufacturers continued to recall ranitidine-containing products.

107. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that NDMA accumulates in ranitidine at unsafe rates when exposed to label-compliant temperature ranges that would occur during normal transport and storage conditions.

108. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine in temperature-controlled vehicles.

109. In response, on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health." The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury." The FDA found that the recall of all ranitidine-containing products and a public warning of the recall was necessary because the "product being recalled presents a serious health risk." The

FDA therefore sent Information Requests to all applicants and pending applicants of ranitidine-containing products "requesting a market withdrawal."

110. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed NDMA levels were higher as the products approached their expiration dates. The FDA's testing eroded the agency's confidence that any ranitidine-containing product could remain stable through its labeled expiration date. Consequently, the FDA withdrew the products from the market. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

111. The FDA's reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned ranitidine-containing products. The European Medicines Agency ("EMA"), the European Union's equivalent to the FDA, through an Article 31 Referral, determined the sale of all ranitidine-containing products should be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA "recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA)." The EMA recognizes NDMA as a probable human carcinogen and issued a "precautionary suspension of these medicines in the EU" because "NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities."

112. The ranitidine molecule itself contains the constituent molecules to form NDMA. Specifically, the O=N (Nitroso) on one side of the ranitidine molecule can combine with the H3C-N-CH3 (DMA) on the other side of the molecule to form NDMA.

113. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the U.S. water supply. Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants were specifically linked to the presence of ranitidine.

114. Ranitidine leads to NDMA exposure in four ways: (1) formation of NDMA in the human digestive system; (2) formation of NDMA due to an enzymatic reaction throughout the human body; (3) formation of NDMA over time under normal storage conditions and which increases significantly when exposed to heat; and (4) formation of NDMA during the manufacturing process.

VII. FORMATION OF NDMA IN THE ENVIRONMENT OF THE HUMAN STOMACH

115. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (0=N) and the DMA molecule (H3C-N-CH3) break off and reform as NDMA.

116. Manufacturer Defendants knowingly, purposely, and deliberately failed to warn Decedent, patients, consumers, medical providers, the FDA, and the public of the increased risk of serious injury and death associated with ingesting OTC Zantac.

117. Decedent would not have taken OTC Zantac had Decedent known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking OTC Zantac.

118. As a direct and proximate result of Defendants' conduct, Decedent suffered serious and permanent injuries, adverse effects and death, which has resulted in significant harms, losses, and damages to Decedent and Plaintiff in sums in excess of the jurisdictional limits of the Court.

VIII. THE FEDERAL REGULATORY LANDSCAPE

119. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[2] and conform to requirements governing the appearance of the label.[3]

120. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[4] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

121. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[5]

122. All drug manufacturers (brand and generic) are also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products."[6] Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time

[2] 21 C.F.R. § 201.5.
[3] *Id.* § 201.15.
[4] *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).
[5] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[6] 21 C.F.R. § 211.166(a).

of dispensing (as directed in the labeling) as well as after they are reconstituted."[7]

123. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates."[8] And expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use."[9] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in § 211.166."[10]

124. Each manufacturer, whether brand or generic, must conduct its own tests to determine and set accurate retest or expiration dates.

125. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[11]

126. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf-life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."[12]

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[7] *Id.*
[8] *Id.*
[9] *Id.* § 211.137(a).
[10] *Id.* § 211.137(b).
[11] 43 Fed. Reg. 45059 (Sept. 29, 1978).
[12] 21 C.F.R. § 211.166(b).

127. After a drug is approved, a manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§ 314.70 and 314.71.

128. Some of the requirements in those regulations require a manufacturer of an approved drug to obtain FDA approval before implementing a label change.[13]

129. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.[14]

130. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[15] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."[16]

131. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"[17]—or to ensure that the drug is shipped and stored under appropriate conditions.

132. A manufacturer of an approved drug can also use the CBE supplement to make "moderate" changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this

[13] *Id.* § 314.70(b).
[14] *Id.* § 314.70(c)(3), (c)(6).
[15] *Id.* § 314.70(c)(6)(i).
[16] 65 Fed. Reg. 83042 (Dec. 29, 2000).
[17] 21 C.F.R. § 211.137(a).

chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."[18]

133. Thus, GlaxoSmithKline, Pfizer, Boehringer Ingelheim, and Sanofi could have made these changes to their several NDAs for Zantac. Any change GlaxoSmithKline made to its Zantac label to strengthen warnings when it first held the NDAs 20-520 and 20-745 would have been passed to Pfizer, Boehringer Ingelheim, and Sanofi when they took over the NDAs. Similarly, any change Pfizer made to its Zantac label to strengthen warnings when it first held the NDAs 20-520, 20-745, and 21-698 would have been passed to Boehringer Ingelheim and Sanofi when they took over the NDAs. Any change Boehringer Ingelheim made to its Zantac label to strengthen warnings when it held the NDAs 20-520, 20-745, and 21-698 would have been passed to Sanofi when it took over the NDAs. Finally, Sanofi had the power to change the labels and warnings for all drugs under OTCs 20-520, 20-745, and 21-698 when it controlled the NDAs.

134. Also, at no time did the Manufacturer Defendants, in concert or individually, seek to make a change to the labels and warnings of OTC Zantac to warn about the risk of cancer associated with NDMA. However, they did seek to make CBE regulation changes to all of these NDAs for other commercial purposes, which were approved by the FDA.

135. Also, a manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."[19]

[18] *Id.* § 314.70(c)(6)(iii)(A), (C), (D).
[19] *Id.* § 314.70 (d)(2)(ix).

136. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf-life data on production batches obtained from a protocol approved in the NDA."[20]

137. At no time did any of the Manufacturer Defendants attempt to include a warning on the labels for ranitidine-containing products such as OTC Zantac that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

138. At no time did any of the Manufacturer Defendants attempt to change their labels on OTC Zantac to delete a false or misleading expiration date, or to add a proper expiration date to ensure that ranitidine-containing products would not break down into NDMA prior to human consumption.

139. Based on the public scientific information, the Manufacturer Defendants knew or should have known that NDMA could form in ranitidine and OTC Zantac by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

140. At no time did any of the Manufacturer Defendants change their labels on OTC Zantac to shorten the expiration date. The Manufacturer Defendants had the ability to unilaterally make such label changes for OTC Zantac without prior FDA approval pursuant to the CBE regulation. Had any of the Manufacturer Defendants attempted such label changes, the FDA would not have rejected them.

141. Because they failed to include appropriate expiration dates on their OTC Zantac products, the Manufacturer Defendants made false statements in the labeling of their OTC Zantac

[20] *Id.* § 314.70 (d)(2)(vi); *see also id.* § 314.70(d)(2)(vii), (x).

products.

IX. FEDERAL LAW REQUIRED THE MANUFACTURER DEFENDANTS TO NOTIFY THE FDA ABOUT THE PRESENCE OF NDMA IN RANITIDINE-CONTAINING PRODUCTS SUCH AS OTC ZANTAC

142. During the time that the Manufacturer Defendants manufactured and sold ranitidine-containing products such as OTC Zantac in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. The Manufacturer Defendants failed to report these risks to the FDA.

143. The Manufacturer Defendants concealed the ranitidine-NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

144. Manufacturers (brand and generic) of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

145. 21 C.F.R. § 314.81(b)(2)(v) provides that the manufacturer's annual report must also contain:

> Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

146. Every approval letter for an NDA issued to GlaxoSmithKline or Pfizer, and transferred to the other Manufacturer Defendants, contained the following directive from the FDA:

> **We remind you that you must comply with the requirements for an approved NDA set forth under 21 C.F.R. 314.80 and 314.81.**

147. The Manufacturer Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their OTC Zantac products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of ranitidine-containing products such as OTC Zantac.

148. The Manufacturer Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of ranitidine-containing products such as OTC Zantac.

149. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any manufacturer, consistent with its heightened obligations to ensure the safety of its products, also should have known about the potential NDMA risks associated with ranitidine consumption.

150. The Manufacturer Defendants never conducted or provided the relevant studies to the FDA, nor did they present the FDA with a proposed disclosure noting the various ways that ranitidine transforms into NDMA. Accordingly, because the Manufacturer Defendants never properly disclosed the risks to the FDA, they never proposed any labeling or storage/transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for transport/storage.

151. When the FDA eventually learned about the NDMA risks posed by ranitidine-containing products, it ordered manufacturers to voluntarily remove the products from the market.

Thus, had any of the Manufacturer Defendants alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove ranitidine-containing products such as OTC Zantac from the market.

X. GOOD MANUFACTURING PRACTICES

152. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("CGMPs") to ensure they meet safety, quality, purity, identity, and strength standards.[21]

153. 21 C.F.R. § 210.1(a) states that the CGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

154. Pursuant to 21 C.F.R. § 211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, all Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine and ranitidine-containing products such as OTC Zantac.

155. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.[22] FDA has also concluded that NDMA can increase in ranitidine under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures,

[21] 21 U.S.C. § 351(a)(2)(B).
[22] Woodcock Letter, *supra* note 38.

including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw ranitidine-containing products altogether.

156. Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring that ranitidine was not exposed to heat or moisture over long periods.

XI. RANITIDINE-CONTAINING PRODUCTS SUCH AS OTC ZANTAC ARE MISBRANDED AND ADULTERATED BECAUSE THEY CONTAIN DANGEROUS AND BIOLOGICALLY RELEVANT LEVELS OF NDMA

157. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[23]

158. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[24]

159. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[25]

160. Among the ways a drug may be adulterated and/or misbranded is: "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[115]

[23] 21 U.S.C. § 331(g).
[24] *Id.* § 331(a).
[25] *Id.* § 331(c).
[115] 21 U.S.C. § 352(j).

161. As recent regulatory action confirms, ranitidine was dangerous to health when used as prescribed.

162. It is unlawful to introduce a misbranded drug into interstate commerce.[116] Thus, the ranitidine/OTC Zantac ingested by Decedent was unlawfully distributed and sold.

163. Decedent purchased brand-name OTC Zantac from Publix from the 1990s to 2018. Decedent ingested the brand-name OTC Zantac that she purchased from Publix over the course of those years.

164. GlaxoSmithKline and Pfizer marketed branded OTC Zantac from 1995 to 1998, which GlaxoSmithKline manufactured. Pfizer then marketed branded OTC Zantac from 1998 to 2006, which GlaxoSmithKline manufactured. Boehringer Ingelheim manufactured and marketed branded OTC Zantac from 2007 to 2016. Sanofi manufactured and marketed branded OTC Zantac from 2017 to 2019. At all times from 1983 to 2019 GlaxoSmithKline marketed prescription Zantac.

165. Decedent, therefore, ingested branded OTC Zantac manufactured or marketed by GlaxoSmithKline, Pfizer, Boehringer Ingelheim, and Sanofi.

166. The OTC Zantac Decedent consumed used the same defective labels devised by GlaxoSmithKline originally and subsequently adopted by Pfizer, Boehringer Ingelheim, and Sanofi.

167. The amount of OTC Zantac Decedent ingested that is attributable to each Manufacturer Defendant was more than de minimis; each Manufacturer Defendants' actions were a substantial contributing factor to Decedent's cancer, subsequent injuries, and eventual death.

ALLEGATIONS OF RECKLESSNESS

168. Defendants' conduct as alleged herein was done with reckless disregard for human

life, oppression, and malice. Defendants were fully aware of the safety risks of OTC Zantac/ranitidine, particularly the carcinogenic potential of OTC Zantac/ranitidine as it transforms into NDMA within the chemical environment of the human body and/or during transport and/or storage.

169. GlaxoSmithKline deliberately developed a dangerous NDMA-contaminated drug, ranitidine, with full knowledge of the risks that NDMA posed, when other formulations were available.

170. The Manufacturer Defendants deliberately crafted and/or failed to update and revise their labels for OTC Zantac and their marketing to mislead consumers such as Decedent.

171. This was not done by accident or through some justifiable negligence. Rather, the Manufacturer Defendants knew they could profit by convincing consumers that OTC Zantac/ranitidine was harmless to humans, and that full disclosure of the true risks of OTC Zantac/ranitidine would limit the amount of money the Defendants would make selling OTC Zantac/ranitidine. The Manufacturer Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading.

172. Defendants failed to inform Decedent of the full risks attendant to ingesting OTC Zantac, and Defendants denied Decedent the right to make an informed decision about whether to purchase and ingest OTC Zantac. Such conduct was done with conscious disregard of Decedent's rights.

TOLLING/FRAUDULENT CONCEALMENT

173. Plaintiff asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling,

delayed discovery, discovery rule and/or fraudulent concealment.

174. Decedent did not learn of the link between her cancer and ranitidine exposure until on or about the year 2020.

175. Decedent would not have taken OTC Zantac had Decedent known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drugs.

176. Upon information and belief, Decedent's physicians were unaware of the increased risk of multiple types of cancer associated with the use of ranitidine due to its transformation into NDMA and, if they had been informed, would have used and prescribed alternative therapies to Decedent.

177. Upon information and belief, Decedent's prescribing physicians would not have prescribed and/or recommended ranitidine-containing products such as OTC Zantac to Decedent, would have changed the way in which they treated Decedent's relevant conditions, changed the way they warned Decedent about the signs and symptoms of serious adverse effects of ranitidine, and discussed with Decedent the true risks of cancer, had the Manufacturer Defendants provided Decedent's physicians with an appropriate and adequate warning regarding the risks associated with the use of ranitidine-containing products such as OTC Zantac.

178. The discovery rule applies to toll the running of the statute of limitations until Decedent knew, or through the exercise of reasonable care and diligence should have known, of facts that Decedent had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

179. Decedent brings this action within the prescribed time limit following Decedent's injuries and Decedent's knowledge of the wrongful cause. Prior to such time, Decedent did not

know and had no reason to know of her injuries and/or the wrongful cause of those injuries.

180. Decedent's Personal Representative, Alexander Omar Valdes, asserts the wrongful death claim in this action, and any alleged expiration of applicable statutes of limitations relates back to the original Complaint filed by the then-living Decedent Teresa Valdes.[26]

181. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Decedent and defects associated with ranitidine-containing products such as OTC Zantac as they transform into NDMA. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of ranitidine. As a result of Defendants' misrepresentations and concealment, Decedent and Decedent's physicians were unaware and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions, that Decedent had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

182. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Decedent could not reasonably have known that Defendants' ranitidine-containing products were and are defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

COUNT I
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against All Manufacturer Defendants)

[26] *Talan v. Murphy*, 443 So. 2d 207 (Fla. 3rd DCA 1983).

183. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in paragraphs 1-182 as if fully stated herein in this paragraph 183.

184. This Count alleges a claim by Decedent for OTC Zantac she consumed and that each Manufacturer Defendant manufactured or sold while controlling the relevant approved NDAs.

185. Under Florida law, a manufacturer or seller has a duty to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

186. At all relevant times, the Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold their OTC Zantac products, which are defective and unreasonably dangerous to consumers, including Decedent, because OTC Zantac does not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of the Manufacturer Defendants.

187. The Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their OTC Zantac products, and in the course of same, directly marketed the products to consumers and end users, including Decedent, and therefore had a duty to warn of the risks associated with the use of OTC Zantac.

188. At all relevant times, the Manufacturer Defendants had a duty to properly design, manufacture, test, market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps as necessary to ensure their OTC Zantac products did not cause users and

consumers, including Decedent, to suffer from unreasonable and dangerous risks. The Manufacturer Defendants had a continuing duty to warn Decedent of dangers associated with OTC Zantac. The Manufacturer Defendants, as a manufacturer or seller of pharmaceutical medication, are held to the knowledge of an expert in the field.

189. The Manufacturer Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as the packaging, storage, and handling of OTC Zantac.

190. At the time each held the controlling NDAs, the Manufacturer Defendants could have provided the warnings or instructions regarding the full and complete risks of ranitidine and OTC Zantac because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

191. Furthermore, after such time as GlaxoSmithKline, Pfizer, and Boehringer Ingelheim held the relevant NDAs, each could have informed all future NDA holders and manufacturers of the risk of cancer-causing NDMA formation and contamination with ranitidine. Any reasonable manufacturers would have undertaken steps to change the labels and warnings.

192. At all relevant times, the Manufacturer Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers, including Decedent, of their products and to those who would foreseeably use or be harmed by the Manufacturer Defendants' OTC Zantac products.

193. Even though the Manufacturer Defendants knew or should have known that ranitidine and OTC Zantac posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with the use and exposure to ranitidine-containing products such as OTC Zantac. The dangerous propensities of ranitidine-containing products such as OTC

Zantac and the carcinogenic characteristics of NDMA, as described above, were known to the Manufacturer Defendants, or scientifically knowable to the Manufacturer Defendants through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product, and were not known to end users and consumers, such as Decedent.

194. The Manufacturer Defendants knew or should have known that ranitidine-containing products such as OTC Zantac created significant risks of serious bodily harm to consumers, including Decedent as alleged herein, and the Manufacturer Defendants failed to adequately warn or instruct consumers, including Decedent, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to ranitidine-containing products such as OTC Zantac. The Manufacturer Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products such as OTC Zantac, and further, have made false and/or misleading statements concerning the safety of ranitidine and OTC Zantac.

195. At all relevant times, the Manufacturer Defendants' OTC Zantac was expected to and did reach Decedent without a substantial change in its anticipated or expected design as manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by the Manufacturer Defendants.

196. Decedent was exposed to the Manufacturer Defendants' OTC Zantac without knowledge of their dangerous characteristics.

197. At all relevant times during her use of Zantac, Decedent read and relied upon the warning labels, instructions, package inserts, and advertisements for OTC Zantac.

198. If Decedent had been warned that ingestion of OTC Zantac could result in an increased risk of cancer, she would have never taken it or would have ceased taking it once she learned this information.

199. At all relevant times, Decedent used and/or was exposed to the use of the Manufacturer Defendants' OTC Zantac while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

200. Decedent could not have reasonably discovered the defects and risks associated with the Manufacturer Defendants' Zantac prior to or at the time Decedent consumed the drugs. Decedent relied upon the skill, superior knowledge, and judgment of the Manufacturer Defendants to know about and disclose serious health risks associated with using the Manufacturer Defendants' products such as OTC Zantac.

201. The Manufacturer Defendants knew or should have known that the minimal warnings disseminated with OTC Zantac were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses, including Decedent.

202. The information that the Manufacturer Defendants did provide or communicate failed to contain relevant warnings, expiration dates, hazards, and precautions that would have enabled consumers such as Decedent to avoid using the drug. Instead, the Manufacturer Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine and OTC Zantac; continued to aggressively promote the efficacy of ranitidine-containing products such as OTC Zantac, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine and OTC Zantac.

203. This alleged failure to warn is not limited to the information contained on OTC Zantac's labeling. The Manufacturer Defendants were able, in accordance with federal law, to comply with relevant state law by disclosing the known risks associated with ranitidine through other non-labeling mediums, *e.g.*, promotion, advertisements, public service announcements, and/or public information sources. But the Manufacturer Defendants did not disclose these known risks through any medium.

204. Had the Manufacturer Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with OTC Zantac, Decedent could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of the Manufacturer Defendants' concealment of the dangers posed by their ranitidine-containing products such as OTC Zantac, Decedent could not have averted her injuries and eventual death.

205. Decedent exercised reasonable prudence and caution when she ingested the Manufacturer Defendants' OTC Zantac products, and Decedent used the Manufacturer Defendants' OTC Zantac products in a manner that the Manufacturer Defendants knew, or should have known, that the product would be used.

206. Decedent did not alter, or caused to be altered, any part of the Manufacturer Defendants' OTC Zantac products that she purchased and ingested.

207. The Manufacturer Defendants' conduct, as described above, was reckless. The Manufacturer Defendants risked the lives of consumers and users of their products, including Decedent, with knowledge of the safety problems associated with OTC Zantac, and suppressed this knowledge from the general public. The Manufacturer Defendants made conscious decisions not to redesign, warn, or inform the unsuspecting public, including Decedent.

208. The Manufacturer Defendants' lack of adequate warnings and instructions accompanying OTC Zantac were a substantial factor in causing Decedent's injuries and death.

209. As a direct and proximate result of the Manufacturer Defendants' failure to provide an adequate warning of the risks of OTC Zantac, Decedent developed colorectal cancer and was injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

WHEREFORE, Plaintiff respectfully requests this Court enter judgment in Plaintiff's favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT II
NEGLIGENCE – FAILURE TO WARN
(Against All Manufacturer Defendants)

210. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in paragraphs 1-182 as if fully stated herein in this paragraph 210.

211. At all relevant times, the Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold OTC Zantac. The Manufacturer Defendants knew or by the exercise of reasonable care should have known that OTC Zantac was not accompanied by adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of the Manufacturer Defendants.

212. The Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, and otherwise released into the stream of commerce their OTC Zantac, and in the course of same, directly marketed the products to

consumers and end users, including Decedent, and therefore had a duty to warn of the risks associated with the use of OTC Zantac.

213. The Manufacturer Defendants owed Decedent a duty to provide adequate warnings about the risks of ingesting OTC Zantac.

214. At all relevant times, the Manufacturer Defendants had a duty to properly design, manufacture, test, market, label, package, handle, distribute, store, and sell, provide proper warnings, and take such steps as necessary to ensure their OTC Zantac did not cause users and consumers, including Decedent, to suffer from unreasonable and dangerous risks. The Manufacturer Defendants had a continuing duty to warn Decedent of dangers associated with ranitidine. The Manufacturer Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

215. The Manufacturer Defendants had a continuing duty to provide appropriate and accurate warnings and instructions regarding the identity, strength, stability, expiry, quality, and purity at the time of use of their products and how to properly store and handle their OTC Zantac.

216. At the time of manufacture, the Manufacturer Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known use of OTC Zantac was dangerous, harmful, and injurious when used by Decedent in a reasonably foreseeable manner.

217. At all relevant times, the Manufacturer Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers, including Decedent, of their OTC Zantac products and to those who would foreseeably use or be harmed by the Manufacturer Defendants' OTC Zantac.

218. The Manufacturer Defendants knew or should have known that OTC Zantac posed a grave risk of harm but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their OTC Zantac products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to the Manufacturer Defendants, or scientifically knowable to the Manufacturer Defendants through appropriate research and testing by known methods, at the time they designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold their OTC Zantac products, and were not known to end users and consumers, such as Decedent.

219. At the time each held the controlling NDAs, the Manufacturer Defendants could have provided the warnings or instructions regarding the full and complete risks of ranitidine and OTC Zantac because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

220. Furthermore, subsequent to such time as GlaxoSmithKline, Pfizer, and Boehringer Ingelheim held the relevant NDAs, each could have informed all future NDA holders and manufacturers of the risk of cancer-causing NDMA formation and contamination with ranitidine. All reasonable manufacturers would have undertaken steps to change the labels and warnings.

221. The Manufacturer Defendants further breached their duty by failing to use reasonable care to adequately warn or instruct consumers (*i.e.*, the reasonably foreseeable users), such as Decedent, of the risks of exposure to their OTC Zantac products. The Manufacturer Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in their OTC Zantac and the potential for ingested ranitidine to transform into the

carcinogenic NDMA compound, and further, have made false and/or misleading statements concerning the safety of OTC Zantac.

222. At all relevant times, Decedent used and/or was exposed to excessive levels of nitrosamines through the use of the Manufacturer Defendants' OTC Zantac while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

223. The Manufacturer Defendants knew or should have known that the minimal warnings disseminated with their OTC Zantac were inadequate. The Manufacturer Defendants failed to communicate adequate information on the dangers and identity, strength, quality, and purity at the time of use of their OTC Zantac products, and the Manufacturer Defendants failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses.

224. At all relevant times during her use of Zantac, Decedent read and relied upon the warning labels, instructions, package inserts, and advertisements for OTC Zantac.

225. If Decedent had been warned that ingestion of OTC Zantac could result in an increased risk of cancer, she would have never taken it or would have ceased taking it once she learned this information.

226. The information that the Manufacturer Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Decedent to avoid using their OTC Zantac products. Instead, the Manufacturer Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine and OTC Zantac; continued to aggressively

promote the efficacy of their products such as OTC Zantac, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting OTC Zantac.

227. A reasonable company under the same or similar circumstance would have warned and instructed of the dangers of OTC Zantac.

228. This alleged failure to warn is not limited to the information contained on ranitidine-containing products' labeling such as the labeling for the Manufacturer Defendants' OTC Zantac products. The Manufacturer Defendants were able, in accord with federal law, to comply with relevant parallel state law by disclosing the known risks associated with OTC Zantac through other non-labeling mediums, *e.g.*, promotion, advertisements, public service announcements, and/or public information sources. But the Manufacturer Defendants did not disclose these known risks through any medium.

229. Had the Manufacturer Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their OTC Zantac, Decedent could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of the Manufacturer Defendants' concealment of the dangers posed by their OTC Zantac, Decedent could not have averted her injuries.

230. The Manufacturer Defendants' conduct, as described above, was reckless. The Manufacturer Defendants risked the lives of consumers and users of their OTC Zantac products, including Decedent, with knowledge of the safety problems associated with ranitidine-containing products such as OTC Zantac, and suppressed this knowledge from the general public, including

Decedent. The Manufacturer Defendants made conscious decisions not to warn or inform the unsuspecting public, including Decedent, of the dangers posed by their OTC Zantac.

231. The Manufacturer Defendants' lack of adequate warnings and instructions accompanying their OTC Zantac caused Decedent's injuries, harms, losses, and damages.

232. As a direct and proximate result of the Manufacturer Defendants' failure to provide an adequate warning of the risks of OTC Zantac, Decedent has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III
STRICT PRODUCTS LIABILITY – PRE-APPROVAL DESIGN DEFECT
(Against GlaxoSmithKline and Pfizer)

233. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in paragraphs 1-182 as if fully stated herein in this paragraph 233.

234. GlaxoSmithKline was the inventor of ranitidine and was the developer of prescription Zantac under NDA 18-709. GlaxoSmithKline was also the developer of the various OTC Zantac products approved under NDAs 20-520 and 20-745, and all supplements. Pfizer was the developer of various OTC Zantac products approved under NDA 21-698 and all supplements.

235. NDAs 18-709, 20-520, 20-745, and 21-698, and their respective supplements, were approved as new NDAs under section 505(b) of the FDCA.

236. GlaxoSmithKline and Pfizer, as inventor and developers, knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Decedent would not have realized the potential risks and dangers of OTC Zantac.

237. GlaxoSmithKline and Pfizer owed a duty to all reasonably foreseeable users to design a safe product.

238. GlaxoSmithKline and Pfizer breached their duty by failing to use reasonable care in the design of OTC Zantac because the drug exposed users to unsafe levels of the carcinogen NDMA.

239. GlaxoSmithKline and Pfizer breached their duty by failing to use reasonable care in the design of OTC Zantac by negligently designing the drug with an inherent susceptibility to form NDMA. Alternative designs of the molecule—designs that were approved by the FDA—existed that substantially reduced the degradation of ranitidine into unsafe levels of NDMA.

240. GlaxoSmithKline and Pfizer breached their duty by failing to use reasonable care in the design of OTC Zantac:

a. When placed in the stream of commerce, OTC Zantac was defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

b. When placed in the stream of commerce, OTC Zantac was unreasonably dangerous in that it was hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, OTC Zantac contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d. GlaxoSmithKline and Pfizer did not sufficiently test, investigate, or study OTC Zantac and, specifically, the ability for OTC Zantac to transform into the carcinogenic compound NDMA within the human body;

e. GlaxoSmithKline and Pfizer did not sufficiently test, investigate, or study OTC Zantac and, specifically, the ability for OTC Zantac to develop

increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

f. Exposure to ranitidine-containing drugs such as OTC Zantac presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

g. GlaxoSmithKline and Pfizer knew or should have known at the time of marketing OTC Zantac that exposure to OTC Zantac could result in cancer and other severe illnesses and injuries;

h. GlaxoSmithKline and Pfizer did not conduct adequate post-marketing surveillance of their OTC Zantac; and

i. GlaxoSmithKline and Pfizer possessed a columnar grade I ranitidine drug substance that was chemically identical to the ranitidine used in the products consumed by Decedent, but was significantly less prone to degrade into NDMA. This morphology of ranitidine was available for use in the United States, but GlaxoSmithKline and Pfizer chose to use an inferior design.

241. GlaxoSmithKline and Pfizer could have employed safer alternative designs and formulations. For example, GlaxoSmithKline and Pfizer could have added ascorbic acid (Vitamin C) to each dose of OTC Zantac, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

242. A reasonable company under the same or similar circumstances would have designed a safer product.

243. Decedent was harmed directly and proximately by the GlaxoSmithKline's and Pfizer's failure to use reasonable care in the design of OTC Zantac. Such harm includes significant exposure to a known carcinogen, NDMA, which can cause or contribute the development of cancers.

244. GlaxoSmithKline's and Pfizer's defective design of OTC Zantac was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the OTC Zantac, including Decedent.

245. The defects in OTC Zantac were substantial factors in causing Decedent's injuries.

246. As a direct and proximate result of the GlaxoSmithKline's and Pfizer's defective design of the OTC Zantac, Decedent has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages, including her death.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV
NEGLIGENCE
(Against All Manufacturer Defendants)

247. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in paragraphs 1-182 as if fully stated herein in this paragraph 247.

248. The products complained of, OTC Zantac, were designed, manufactured, advertised, marketed, distributed, and/or sold by the Manufacturer Defendants, which Decedent regularly used and ingested in her daily life.

249. Each of the Manufacturer Defendants owed a duty to Decedent and the general public to manufacture and sell only products that were reasonably safe for their intended use, and to refrain from selling any product that was unreasonably dangerous and that posed an unreasonable threat of bodily harm to consumers and users such as Decedent and/or others and to assure that OTC Zantac remained safe and free from any defects and/or unreasonable risks of danger to the consumers such as Decedent who would ingest OTC Zantac.

250. Each of the Manufacturer Defendants breached said duty to Decedent by negligently making OTC Zantac, which contained NDMA and which further created additional NDMA once ingested and then, further negligently placing OTC Zantac into the stream of commerce. OTC Zantac was unreasonably dangerous and hazardous to the public, including Decedent.

251. Decedent was exposed to the Manufacturer Defendants' products whenever she took OTC Zantac. Each exposure to the Manufacturer Defendants' OTC Zantac caused Decedent to be exposed to additional and accumulating NDMA, which then resulted in and directly caused Decedent to suffer severe bodily injuries, specifically colorectal cancer. Each exposure to OTC Zantac was harmful and caused or contributed substantially to Decedent's injuries. Decedent's injuries arose out of, were connected to, and caused by the design, manufacture, advertisement, marketing, distribution, and/or sale of the Manufacturer Defendants' OTC Zantac products.

252. Decedent was exposed to and did ingest OTC Zantac products which were designed, manufactured, advertised, marketed, distributed, and/or sold by the Manufacturer Defendants.

253. Decedent's damages as alleged herein are the direct and proximate result of the negligence of the Manufacturer Defendants in that they produced, sold, and otherwise placed into the stream of intrastate and interstate commerce OTC Zantac products that the Manufacturer Defendants knew, or, in the exercise of ordinary and reasonable care should have known, were deleterious and highly harmful to Decedent's health and wellbeing. The Manufacturer Defendants, prior to selling and/or distributing their OTC Zantac products to which Decedent was exposed, knew or should have known that exposure to OTC Zantac was harmful to human beings and that it could cause injuries including, but not limited to colorectal cancer leading to death. The

Manufacturer Defendants also knew that their customers and the consumers of OTC Zantac, including Decedent, would use and be exposed to the Manufacturer Defendants' OTC Zantac products in such a way as to cause their customers, including Decedent, to ingest OTC Zantac, which would further expose their customers such as Decedent to additional amounts of NDMA after ingestion.

254. The Manufacturer Defendants' OTC Zantac products contained defects known to, or that should have been known to, the Manufacturer Defendants but were defects that were latent and unknown to the ordinary consumer, including Decedent. The NDMA that was in the Manufacturer Defendants' OTC Zantac and which was further created in the body of consumers after ingestion were latent defects at the time they were manufactured and at the time Decedent was exposed to them in that OTC Zantac contained and created the NDMA carcinogen, which the Manufacturer Defendants knew, or in the exercise of reasonable care should have known, would cause injuries to consumers such as Decedent including, but not limited to, colorectal cancer.

255. The Manufacturer Defendants knew that their OTC Zantac products would be used by their customers, such as Decedent, without inspection for defects and that any such inspection would not have advised Decedent of the fact that the Manufacturer Defendants' OTC Zantac products could cause the injuries which she suffered. Such facts made the Manufacturer Defendants' OTC Zantac products inherently and unreasonably dangerous in that Decedent was not apprised of, could not and would not contemplate the danger and/or the extent of the danger of contracting colorectal cancer and the associated injuries and complications as a result of her exposure to the Manufacturer Defendants' OTC Zantac and NDMA.

256. Decedent used and ingested the Manufacturer Defendants' OTC Zantac products in the manner in which they were intended or reasonably foreseeable to the Manufacturer Defendants.

257. The Manufacturer Defendants' OTC Zantac products failed to perform as safely as Decedent expected they would, in that they caused her to develop injuries including, but not limited to, colorectal cancer and the injuries alleged herein.

258. The Manufacturer Defendants engaged in the conduct described herein above, which conduct fell below a reasonable standard of care, and did so with such gross negligence as to indicate a willful and wanton disregard for the rights of others, including Decedent, and knowingly continued to manufacture and sell a product with defects known to the Manufacturer Defendants as to indicate a willful and wanton disregard for the rights of others, including Decedent.

259. As a direct and proximate result of the conduct of the Manufacturer Defendants, as described in the preceding paragraphs, Decedent developed colorectal cancer and the injuries alleged herein.

260. As a direct and proximate result of the conduct of the Manufacturer Defendants, Decedent suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money, aggravation of a previously existing condition, and death.

WHEREFORE, Plaintiff demands judgment against the Manufacturer Defendants, jointly and severally, for compensatory damages and the costs of this action and furthermore demands trial by jury of all issues so triable as of right.

COUNT V
NEGLIGENCE
(Against Publix)

261. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in paragraphs 1-182 as if fully stated herein in this paragraph 261.

262. This Count alleges claims against Publix for negligence in shipping, transporting, distributing, and storing OTC Zantac. This Count does not allege claims against Publix for failing to warn consumers of the risks of developing NDMA and cancer in individuals who ingest OTC Zantac or private label ranitidine or for defects related to the design and manufacture of OTC Zantac or private label ranitidine.

263. Whether a pharmacy or a store has a single location or is one location out of thousands in a giant nationwide retail network, retailers and pharmacies such as Publix that sell prescription and OTC therapeutics must act in a reasonable manner that is in the best interests of their patients and customers.

264. Publix employs numerous pharmacists who advise patients concerning prescription medicines would have access to expert knowledge about routes of administration, potential side effects, and adverse events (AEs) of medications. The pharmacist would be knowledgeable of and in a position to supervise the adequacy of the supply chain of prescription and OTC medications from manufacturer to patient/consumer. A pharmacist is a highly trained professional scientist with high level knowledge of pharmacology and chemistry. As such, a pharmacist would be expected to understand how medications are synthesized and formulated for ingestion by the patient. In particular, the quality of each medication including but not limited to its stability at elevated temperature should be validated prior to supplying a drug manufacturer's therapeutic to patients.

265. Publix, because of their knowledge and background in developing and selling private label versions of numerous drugs (i.e. selling drugs under their own brand name), have experience in drafting and enforcing complex contracts with manufacturers that address audits, quality control, packaging, manufacturing best practices, testing, inspections, shipping, transportation, storage, and other requirements for OTC medications such as OTC Zantac.

266. Publix sold private label versions of ranitidine (for example, Publix Maximum Strength Ranitidine). In the course of bringing their private label ranitidine to market, Publix had a duty to—and did—review relevant studies on the safety of ranitidine. Publix had a duty to—and did— study the heat and humidity limits on the label for ranitidine products.

267. At all relevant times, Publix knew or should have known that many drugs are sensitive to decomposition into potentially toxic byproducts when exposed to humidity and elevated temperatures as compared with Controlled Room Temperature ("CRT"), 68° to 77° F or 20° to 25° C.

268. The U.S. Pharmacopeia Convention (hereinafter "USP"), Chapter 1079, entitled "Good Storage and Shipping Practices," states that "[g]ood storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products," including retailers. USP 1079 also states that "all organizations along the supply chain bear responsibility for ensuring that they handle drug products within adequate storage and distribution parameters that will not affect the drug product identity, strength, quality, purity, or safety."

269. Publix knew or, in the exercise of reasonable care, should have known that ranitidine degrades in the presence of heat and humidity. As sellers of drugs, Publix knew or, in

the exercise of reasonable care, should have known that storing drugs outside the range required on the label can pose serious health risks.

270. Based on the available scientific evidence, at all relevant times, Publix knew or, in the exercise of reasonable care, should have known that a compound such as ranitidine was unstable, degraded, and was a source of NDMA, a known carcinogen.

271. Based on the available scientific evidence, at all relevant times, Publix knew or, in the exercise of reasonable care, should have known that use of ranitidine-containing products such as OTC Zantac could cause or be associated with Decedent's injuries, and thus create a dangerous and unreasonable risk of injury to the users of these products, including Decedent.

272. Publix knew or, in the exercise of reasonable care, should have known that ranitidine is a time and temperature-sensitive pharmaceutical product that degrades in the presence of heat and humidity or develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage.

273. Testing of the quantity of NDMA in ranitidine performed to date has shown substantial variation among different batches. Some ranitidine has much more NDMA when tested, and some has less.

274. NDMA forms due to chemical reactions in the human body, and degradation before consumption (principally heat, humidity, or time). Testing is performed before consumption and the age of the ranitidine is documented, so neither time nor degradation in the body should produce substantial variation. The best inference must be that substantial variation in heat and humidity is causing differing amounts of NDMA to form.

275. Different ranitidine-containing products that Publix sold may have listed slightly different storage and transportation requirements, but a common label requirement was "store at 20°C to 25°C (68°F to 77°F)" and "avoid excessive heat or humidity."

276. As sellers and dispensers of prescription pharmaceutical products and over-the counter drugs, Publix knew or, in the exercise of reasonable care, should have known that storing drugs outside the range required on the label can pose serious health risks.

277. At all relevant times, Publix was well aware of the need to maintain sensitive pharmaceutical drugs under proper shipping and storage conditions, and that maintaining the highest safety techniques is best for the consumer. Prescription and OTC pharmaceutical transportation companies are well aware of the importance of precise temperature control down to the degree, and advertise on their ability to provide precise, quality service. More precise, colder transportation is more expensive than less precise, warmer transportation.

278. Publix knew or, in the exercise of reasonable care, should have known through stability testing that NDMA levels in ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. The Retailer Defendants knew or, in the exercise of reasonable care, should have known through testing that NDMA levels are higher as ranitidine-containing products such as OTC Zantac approached their expiration dates. Publix knew or, in the exercise of reasonable care, should have known that ranitidine-containing products such as OTC Zantac would not likely remain stable through their labeled expiration dates.

279. Publix also knew that their retail stores and pharmacies where consumers such as Decedent purchased OTC Zantac were in or near Miami-Dade County, Florida, which is notoriously hot and humid. Temperatures in Miami-Dade are far hotter and more humid than those in most of the United States and routinely exceed 77°F.

280. Despite that knowledge, Publix transported OTC Zantac to their stores in trucks that were not temperature controlled. Decedent purchased OTC Zantac from Publix's stores that had been transported in trucks that were not temperature controlled.

281. In doing so, Publix systematically exposed OTC Zantac, including the OTC Zantac that Decedent purchased from the Publix's stores and ingested, to excessive levels of heat and humidity that violated the instructions on the products' labels.

282. Publix failed to implement rigorous policies and procedures to ensure substantial compliance with the heat and humidity requirements on OTC Zantac product labels in the Florida heat. This failure led to widespread noncompliance, and Publix systematically exposed ranitidine-containing products such as OTC Zantac to excessive levels of heat and humidity that violated the instructions on the products' labels.

283. For example, Publix shipped ranitidine-containing products through the mail. This method of transportation—whether through the United States Postal Service or large common carriers such as FedEx and UPS—does not guarantee controlled temperature or humidity.

284. In fact, numerous publicly available news articles confirm that the temperature in mail trucks is not controlled and can exceed 120 degrees. *E.g.*, Jeff Kronenfeld, *Most Postal Trucks Don't Have Air Conditioning. That's Bad News for Birth Control*, Vice (Oct. 1, 2019) https://www.vice.com/en/article/9kedp5/most-postal-trucks-dont-have-air-conditioning-thats-bad-news-for-birth-control (noting that birth control, which, like ranitidine should be stored between 68 and 77 degrees, often exceeds that temperature in trucks during shipping).

285. An FDA study in 1995 showed that the interior temperature of mailboxes exceeded 136 degrees on a 100-degree-day. *See* J.C. Black and T. Layloff, *FDA Division of Drug Analysis,*

Summer of 1995 – Mailbox Temperature Excursions in St. Louis, http://www.layloff.net/articles/1995%20Mailbox%20Temp%20in%20STL.pdf.

286. Publix systematically exposed ranitidine-containing products such as OTC Zantac to excessive levels of heat and humidity that violated the instructions on the products' labels. Different ranitidine-containing products listed slightly different storage and transportation requirements, but a common label requirement was "store at 20°C to 25°C (68°F to 77°F)" and "avoid excessive heat or humidity."

287. Publix transported OTC Zantac, including the OTC Zantac that Decedent purchased at the Publix's stores and ingested, in trucks that were not temperature or humidity controlled, and the OTC Zantac Publix transported would reach high temperatures and high levels of humidity when it was shipped to Miami-Dade County.

288. Defendant Publix knowingly and negligently accepted and allowed:

a. the transportation of OTC Zantac to its stores in tractor trailers lacking CRT;

b. the transportation of OTC Zantac to its stores in tractor trailers lacking temperature sensing equipment as well as lacking CRT; and

c. the delivery of OTC Zantac to its stores in closed tractor trailers on sunny, warm days where internal temperatures in its tractor trailers could reach or exceed 130° F.

289. Defendant Publix has temperature sensors and CRT environmental control capabilities in many of its warehouses and distribution centers, yet Defendant Publix allowed OTC Zantac to be stored for extended periods of time at Defendant Publix's warehouses and distribution centers that did not have temperature sensors or CRT environmental control capabilities. Defendant Publix stored OTC Zantac for extended periods of time at its distribution centers in Florida and Georgia that were not temperature or humidity controlled.

290. Publix, directly or indirectly, transported, stored, handled, shipped, distributed, and/or sold OTC Zantac that Decedent purchased and ingested.

291. Publix knew or, in the exercise of reasonable care, should have known that users and consumers of OTC Zantac such as Decedent were unaware of the risks and the magnitude of the risks associated with use of OTC Zantac and the unreasonable danger and risk of ingesting OTC Zantac that had been shipped and stored without temperature-controlled conditions.

292. Publix knew or, in the exercise of reasonable care, should have known that it was foreseeable that consumers such as Decedent would suffer injuries as a result of the Publix's failure to exercise reasonable and ordinary care in the handling, distribution, shipping, transportation, storage, and/or sale of ranitidine-containing products such as OTC Zantac.

293. Publix had a duty to exercise reasonable care in the storage and transportation of OTC Zantac products to ensure the OTC Zantac products were not unreasonably dangerous to consumers and users such as Decedent.

294. Publix breached that duty. It did not ensure that OTC Zantac was stored at low humidity or within the temperature range on the label. Instead, OTC Zantac was subjected to excessive humidity and heat during storage, transportation, and shipping, which caused the drug to degrade leading to the formation of excessive levels of NDMA.

295. Publix was unreasonable and reckless in ignoring the risks of NDMA forming.

296. Decedent did not know the nature and extent of the injuries that she would suffer and that could result from the intended use of and/or exposure to OTC Zantac that she purchased at the Publix's stores and ingested.

297. As a direct and proximate result of the negligence and conduct of Publix, as described in the preceding paragraphs, Decedent developed colorectal cancer and the injuries alleged herein.

298. As a direct and proximate result of the negligence and conduct of Publix, Decedent suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money, aggravation of a previously existing condition and death.

WHEREFORE, Plaintiff demands judgment against Publix for compensatory damages and the costs of this action and furthermore demands trial by jury of all issues so triable as of right.

COUNT VI
WRONGFUL DEATH
(Against All Defendants)

299. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in paragraphs 1-182 as if fully stated herein in this paragraph 299.

300. Decedent died from colorectal cancer on July 27, 2022.

301. Decedent's death was the direct and proximate result of the negligent acts and omissions of Defendants.

302. At all times material hereto, Defendants adopted design and manufacturing processes for OTC Zantac which were not common, usual, customary, prudent, or safe in accordance with established industry standards relating to the design and manufacture of similar consumer products with similar reasonably foreseeable functions.

303. At all times material hereto, the ranitidine-containing products were designed, manufactured, transported, and sold to consumers including Decedent without consideration for

drug safety while being used under the intended or reasonably foreseeable conditions and in the intended manner.

304. Defendants designed, manufactured and placed OTC Zantac into the stream of commerce, intending that it be used in the precise manner that it was used by Decedent.

305. At all relevant times, Defendants knew or should have known that OTC Zantac is sensitive to decomposition into potentially toxic byproducts when exposed to humidity and elevated temperatures as compared with Controlled Room Temperature ("CRT"), 68° to 77° F or 20° to 25° C, resulting in the formation of NDMA.

306. As described with specificity above, Defendants knew or should have known that their ranitidine products, including OTC Zantac, posed an unacceptable risk of creating NDMA prior to being consumed by intended users including Decedent.

307. At all relevant times, Defendant knew or should have known that NDMA is a cancer-causing carcinogen, hazardous to human health.

308. Notwithstanding such knowledge, Defendants continued to manufacture, transport, and sell OTC Zantac to consumers.

309. Defendants represented to the public and to Decedent that OTC Zantac was safe for continued consumption.

310. Defendants owed a duty to Decedent to exercise reasonable care in ensuring that OTC Zantac was safe for consumption by end-user consumers including Decedent.

311. Defendants' actions proximately contributed to or caused injuries to Decedent including but not limited to a slow and painful death caused by colorectal cancer.

312. Defendants' actions proximally contributed to or caused injuries to Plaintiff as survivor and Personal Representative of the Estate of Decedent.

313. But for Defendants' actions, Decedent would not have developed the cancer that ultimately caused her death.

WHEREFORE, Plaintiff, as the Personal Representative for the Estate of Teresa Valdes, deceased, hereby demands judgment for compensatory damages, costs, prejudgment and post-judgment interest, and such other and further relief as the Court may deem appropriate under the circumstances. Plaintiff further demands a trial by jury. Plaintiff hereby demands damages for all survivors due under Florida's Wrongful Death Statute.

PRAYER FOR RELIEF

Plaintiff requests the Court to enter judgment in Plaintiff's/Decedent's favor and against Defendants for:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. pre-judgment and post-judgment interest;

c. reasonable attorneys' fees as provided by law;

d. costs and expenses of these actions;

e. reasonable damages for all survivors due under Florida's Wrongful Death Statute;

f. statutory damages and other relief permitted by law that will govern these actions; and

g. any other relief the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury of all issues so triable as a matter of right.

DATED: June 27, 2023

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CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a complete copy of the foregoing has been filed with the Florida Courts e-filing portal this 27th day of June, 2023, which will serve copies on all counsel of record.

/s/ Justin Parafinczuk
Justin Parafinczuk